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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,719	08/22/2000	Margret Hoehe	101195-2	8381

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,719	HOEHE ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 34-43* is/are pending in the application.

4a) Of the above claim(s) *2,4-8,22,37,38,40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9-21,23,34-36,39,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that Applicant's amendments received 12/2/04 have been entered in full.

Claims 2, 4-8, 22, 37, 38, 40, 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim, as set forth previously.

Applicant is notified that any outstanding rejection or objection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Response to Amendments and Arguments:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34, 35, 36, 39, and 43 are rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter. The claims read on the DNA that would be present in a human being and are thus not patentable under 35 USC 101. Regarding Applicant's arguments, Applicant is reminded that claims 34, 35, 36, 39, and 43 depend from claim 9 and not from claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and dependent claim 3 require a polynucleotide encoding the sequence of a human beta2-adrenergic receptor gene. The use of the word "encoding" in the claim is confusing because it requires that one polynucleotide encode another, the art does not recognize the use of this word in that way, and it is thus unclear what limitations are placed on the claim as it is worded. Applicant is notified that replacing the word "encoding" with the word "comprising" would obviate this grounds of rejection.

In Claim 39, the phrase "The genomic DNA variant" lacks anteceded ant bases, thus the artisan would not know which genomic DNA variant was "The genomic DNA variant". Additionally the word "variant" renders the claims indefinite because the term is a relevant term and the specification does not set forth the degree to which the claimed subject matter is allowed to vary; thus the artisan could not reasonably be sure that he or she was in possession of what is claimed. Note that the word "variants" as it is used in claim 17 is definite, as the word denotes a concept rather than that which is being claimed.

Claims 1, 9-12, 23, 34, 35, 36, 42, 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining the disposition to

hypertension by detecting the presence of the 1541T, 1568T, 1633A, 1666C allele of SEQ ID NO: 1 and determining the disposition to asthma by detecting the presence of the 1633 allele (as taught by Turki et al.), does not reasonably provide enablement for methods of determining the disposition to any diseases other than hypertension and nocturnal asthma or by detecting any other than the 1541T, 1568T, 1633A, 1666C alleles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, as set forth previously and recast below in view of Applicant's amendments.

Claims 19 requires determining any aspect of the autonomic nervous system while claim 23 requires predicting the survival time after such diverse diseases as stroke, myocardial infarct, cardiac failure and/or apoplexy, yet the specification has provided evidence only involving hypertension, i.e. page seven. Further, TURKI et al., J. Clin. Invs. 95(1635-1641)1995 disclose bases changes at positions 1633, 1666, and 2078, of the human beta2 adrenergic receptor gene and further indicate that an allele harboring the 1633 mutation is correlated with nocturnal asthma (see page 1637). The specification however, simply speculates that the these mutations would underlie a host of other, seemingly disparate disease states. If this were indeed true, then one wonders how these diseases would have escaped the notice of TURKI et al. when they conducted their clinical investigations. Regardless, the specification has simply presented an invitation to the artisan to begin an essentially random trial and error plan of extensive experimentation, of the type conducted by TURKI, wherein patients with any disorder are tested for these mutations in the hope of finding a correlation. "Tossing out the mere germ of an idea does not constitute enabling disclosure... [R]easonable detail must be provided in order to enable

members of the public to understand and carry out the invention." Genentech, Inc. v. Novo Nordisk Inc., 108 F.3d 1361, 1366, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997).

The claims are in essence single means claims because the specification offers only a single means, i.e. detecting the presence of a particular allele, 1541T, 1568T, 1633A, 1666C and correlating it with a single disorder, i.e. hypertension, yet the claims encompass a tremendous diversity of alleles that are required to be used to determine the disposition to an immensely vast genus of disparate disease states.

In *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification at most disclosed only those means known to the inventors. When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See also *Fiers v. Sugano*, 984 F.2d 164, 25 USPQ2d 1601 (Fed. Cir. 1993), and MPEP § 2164.08(a).

Further, the specification has failed to teach how to use polynucleotides of claims 1, 34, 35, 36, 42, 43 without undue experimentation. The specification fails to assert that these alleles are correlated with any particular disorder of phenotype (with the exception of the 1541T, 1568T, 1633A, 1666C allele), thus the invitation to find such, as discussed above, is unduly burdensome.

Therefore, due to the large amount of experimentation required to find other correlations between the myriad allele types presented in the specification and the myriad of disease types speculated by the specification to correlate with the alleles, if such correlations can be found, the

complex nature of the autonomic nervous system, the lack of particular information provided by the specification, e.g. allele X correlates with disease Y, the apparent contradictory state of the art as exemplified by TURKI et al., who conducted a clinical trial with patients having alleles recited in the specification yet failed to notice other diseases associated with the alleles, the breadth of the claims which encompass almost every conceivable metabolic disease, it would require undue experimentation by one skilled in the art to make and use the invention commensurate in scope to that which is claimed.

It is noted that all but claims 19 and 23 have been amended to limit the disorders to hypertension. Applicant has not addressed the rejection regarding claims 19 and 23. Furthermore, as noted above the specification has not provided sufficient guidance as to how to use the scope of polynucleotides claimed in claims 1, 34, 35, 36, 42, 43 and detected in claims 9-13, 17-21, 23 (note the open language, i.e. "at least" , e.g. claim 10). Applicant does not address this aspect of the rejection.

Conclusion

This application contains claims 1, 2, 4-23, 34-43 are drawn to an invention nonelected with traverse or encompass nonelected subject matter. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (571) 272-0829. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER

February 18, 2005